EXHIBIT

“C”

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO: ***Lula Fender v. Ethicon, Inc., et al.*** ***2:12-cv-06182***	**HON. JOSEPH R. GOODWIN**

RULE 26 EXPERT REPORT OF DR. WILLIAM PORTER, M.D.

A. Qualifications and Background.

My name is William Edward Porter, M.D. I received a bachelor's degree in biology at the University of Michigan located in Ann Arbor, MI. I then went on and obtained a medical degree from the Wayne State University located in Detroit, MI. I subsequently completed a residency in obstetrics and gynecology at the University of Cincinnati and an American Board of Obstetrics and Gynecology certified three-year fellowship in Female Pelvic Medicine and Reconstructive Surgery (FPMRS) at the University of Tennessee Medical Center located in Memphis, Tennessee. I am one of the first ABOG Certified Physicians in the United States in the Field of (FPMRS). I served as a reviewer for the International Urogynecology Journal (2003 to 2006). I am currently a journal reviewer for Female Pelvic Medicine & Reconstructive Surgery. I serve on the American Urogynecology Society Coding Committee (2012 to 2016). I have lectured locally, nationally, and internationally on many subjects in the field of urogynecology and reconstructive pelvic surgery, including pelvic organ prolapse and urinary incontinence. I have taught at many medical device industry sponsored labs, the purpose of which has been to instruct other surgeons on the proper use of surgical devices and tools to treat pelvic organ prolapse and stress incontinence. I have also worked as a consultant to many medical device companies in developing and validating new products in the pelvic floor space.

I am trained extensively and practice exclusively in the field of pelvic medicine. This field encompasses pelvic organ prolapse, urinary incontinence, fecal incontinence, pelvic pain and

pelvic floor dysfunction. Over the past 14 years post residency, I have performed nearly 3,000 pubovaginal slings (synthetic and xenographic) and fascia latta bladder neck slings. I have performed several thousand vaginal repairs for pelvic organ prolapse using native tissue, allograph, xenograph or synthetic augmented repairs. In the same regard I have also removed slings and mesh complicated surgeries (erosion and/ extrusion).

I have been specifically trained to use pelvic organ products (slings, graphs and mesh kits) by the following companies: C. R. Bard, Boston Scientific, Mentor, Cook Medical, Gynecare, American Medical System and Coloplast. I did complete any training required by said companies. I have been a trained proctor for the following companies: C.R. Bard, Boston Scientific, Mentor, Cook Medical, Gynecare and Coloplast. I have specifically treated female patients with the TVT mid-urethral sling.

Based upon my work as a urogynecologist (FPMRS), I am familiar with the medical complications that are generally associated with mesh repair surgery, and I am experienced in the recognition, diagnosis and treatment of patients suffering from complications caused by pelvic repair mesh implants and mid-urethral slings. The focus of my evaluation is the role that the TVT played in causing injury to Ms. Fender. The most common mesh-related complications are pelvic pain, scarring in the vagina and pelvic floor, pain into the legs and thighs, dyspareunia, chronic inflammation of tissue, chronic vaginal discharge or bleeding, scar bands or scar plates in the vagina, vaginal shortening or stenosis, erosion of mesh into tissues or organs, and nerve entrapment. In diagnosing and treating patients with mesh related complications, I often determine the likely cause of the patient's complications based upon a differential diagnosis, which typically includes a physical and history and a review of her medical records and other information about the patient.

In formulating the opinions set forth in this report I have relied on my personal knowledge, education and training, prior experience in treating stress urinary incontinence, medical literature, and a review of relevant medical records pertaining to Ms. Fender. All of my opinions are true and correct to the best of my knowledge. I do reserve the right to supplement this report and my opinions if additional information becomes available (reports, discovery, articles or other relevant information). I also reserve the right to perform a physical examination on Ms. Fender.

B. Summary of Materials Reviewed

I have reviewed the following medical records and depositions with accompanying exhibits pertaining to Lula Fender:

Colquitt Regional Medical Center

Moultrie Urology

David Baddour, MD

Billy Price, MD

Betty Koukis, M.D.

Frank Glover, Jr., M.D.

Deposition of Lula Fender

Plaintiff Profile Form and Plaintiff Fact Sheet of Lula Fender

C. Summary of Medical Facts related to Lula Fender

DOB: 12/29/1951

Past Medical History:

Diabetes, Diverticulitis, Heart disease, Hypertension, GERD, Schizophrenia, Depression, Renal Stones, Pulmonary Embolus, Fibromyalgia

Past Surgical History:

Breast Biopsy, C-section, Endometriosis, Hysterectomy (1984), Bladder Neck Surgery (1986)

Social:

Disabled

Medications:

Advair, Xanax, Lasix, Provigil, Humalog, Metformin, Neurontin, Ventolin, Vesicare, Xanax, Atenolol, Lasix

10/23/2003

She had a TVT as well as exploratory Laparotomy with tubes and ovaries.

9/22/2005

She had presented to the office for vaginal itching and burning. She had a vaginal exposure.

10/11/2005

The sling was excised from a band like area (1.5 cm).

11/10/2005

She was seen in the office postoperatively. Her incision was healed. She had exposure of her mesh in the midline versus left.

2/10/2009

She has a brown discharge.

3/26/2009

Foreign body mesh in anterior vaginal wall with grade 2 cystocele.

5/14/2009

She had stress incontinence with a maximum flow rate (14 ml/s). She has a small bladder capacity.

6/22/2009

She continues to have stress incontinence. She wakes up wet every morning. She reports that she cannot tolerate any sexual intercourse. Mesh erosion noted.

7/10/2009

She had a transvaginal sling procedure and anterior colporrhaphy.

12/13/2011

UTI, OAB with urge incontinence. She was treated with an antibiotic and Vesicare.

8/22/2012

Pseudomonas UTI

2/26/2013

Recurrent UTI was remarked in her chart

D. Methodology and Analysis.

In determining the cause of a specific injury, it is customary to "rule in" potential causes of the injury, and then by process of elimination, to "rule out" the least likely causes to arrive at the most likely cause. This process is known as differential diagnosis, or differential etiology, and it is a well-established and universally accepted methodology for determining the cause of injuries employed by physicians throughout the United States. I often determine the cause of a patient's complications based upon an interview with the patient, a review of her medical records or knowledge of her prior medical history. I have used that methodology in arriving at my opinions in the case.

During her visits she reports having dyspareunia that prevented her from coitus. Meyer et al reports dyspareunia rates of 36% at a 5 year follow up from mesh surgery. On the other hand Alperin et al reports a dyspareunia rate of 28.9%, which was similar to preoperative rate. Porter et al reports a site-specific posterior repair tends to have a positive affect on dyspareunia 73% cured vs. 19% where it increased.

As the vagina is a cleaned contaminated area, there is no way to completely eliminate bacteria from the surgical site. Implantation though this dirty field could allow bacteria to attach. These bacteria then can attach to the mesh and secrete a biofilm or a polysaccharide slime excreted by the bacteria. This slime could prevent the host defensive mechanism from clearing the infection. (Edmiston). This tissue response can contribute to the cause of vaginal pain, pelvic pain and chronic inflammation. This chronic inflammation/infection could be a source of pain. This chronic inflammation/infection could be a source of an erosion, vaginal discharge and possible UTI's. Dr. Daniel Elliott in his general expert report suggested the mesh creates a foreign body reaction and a chronic inflammatory response that can lead to chronic pain in the patient. The body's foreign body response to the mesh can cause a severe and chronic inflammatory reaction leading to excessive scarring in and around the mesh. Dr. Bruce Rosenzweig of the general expert witness group suggests that mesh degrades over time and causes a chronic foreign body reaction, fibrotic bridging, mesh contracture/shrinkage, fraying, particle loss, roping and curling of the mesh contributing to pain. Ethicon's Daniel Burkley, a Principal Scientist has testified that polypropylene mesh in human beings is subject to some degree of surface degradation

In considering the cause of the vaginal pain and dyspareunia suffered by Lula Fender, her TVT sling contributed to her pain and vaginal scarring. She reports pain over the sling on examination. On physical examination the patient had exposed TVT sling. She had the exposed TVT excised from a band like area (1.5 cm). This is from what Dr Rosenzweig's refers as a chronic inflammation from the mesh. She also had a second occurrence of erosion of her TVT sling.

The next step in my analysis was to rule out other potential causes. I did consider other potential causes including post-op scarring and granulation tissue from her c-section, hysterectomy and previous bladder neck surgery. I also considered other factors in her history including her previous pelvic and abdominal surgery. I did consider her medical problems: Diabetes, Diverticulitis, Heart disease, Hypertension, GERD, Schizophrenia, Depression, Renal Stones, Pulmonary Embolus, Fibromyalgia. I considered each of these other risks for her pain, mesh erosion and dyspareunia and I concluded that they could be ruled out as a source of her vaginal pain, mesh erosion and dyspareunia suffered by Lula Fender.

Additionally, it is my opinion to a reasonable degree of medical and scientific certainty, based on my background, education, training and experience, that Lula Fender's treating physicians who implanted met the standard of care during implantation of the device. I found no evidence of surgical error or deviation from the requisite procedural steps. Further, after reviewing the operative reports, I see no evidence of any surgical complications.

E. Conclusion.

Based on the foregoing analysis, and based on my education, training and knowledge, it is my opinion to a reasonable degree of medical probability that the cause of Ms. Fender' s pain, mesh erosion, and dyspareunia is related to her TVT Mesh Implant. This is related to what Dr. Elliott described as a chronic inflammation around the mesh causing a banding of the sling. As per Dr. Klinge opinion there may be safer alternatives to Gynecare's polypropylene (i.e. laser cut

technology (less fraying) or different materials (PVDF). Ethicon's is designed to cause a greater than necessary inflammation and foreign body reaction as is occurring in Ms. Fender.

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I have the right to supplement and amend this opinion should additional factual information be forwarded to me that I did not have available at the time this opinion is submitted.

Dated this the 22th day of May, 2017.

William Porter, M.D.